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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,789	05/15/2001	Pablo Rubinstein	63475/267	9553

7590 07/13/2004

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EXAMINER	
BIANCO, PATRICIA	

ART UNIT	PAPER NUMBER
3762	16

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/855,789	RUBINSTEIN ET AL.	
	Examiner	Art Unit	
	Patricia M Bianco	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25 and 27-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25 and 27-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25, 27, 28, 33-39, 41-43, 48-52, 54-56, 61, 62, 64-66, 71 and 73 are rejected under 35 U.S.C. 102(b) as anticipated by Boyse et al. (5,004,681). It is the position of the examiner that the "therapeutic product" claimed is mostly separated white blood cells and a cyroprotective agent. Boyse et al. discloses cryopreservation of hematopoietic stem and progenitor cells (i.e. white blood cells) of blood therefore anticipates the claimed invention. The cells may be obtained from cord blood and/or placental blood (col. 12, lines 54-60). The blood had an anticoagulant, such as ACD, added to it and therefore the separated cells will inherently have residual anticoagulant in the product. The cells also will have a cyroprotective agent added to them, such as DMSO or dextran. With respect to the use of DMSO, Boyse et al. states that a low concentration of DMSO is used (col. 12, lines 25-68). It appears that applicant is intending to define the invention by the method of making the product (see below for further explanation). The method of making in a product claim is not germane to the issue of patentability of the product itself. Therefore, the above noted intended use limitations and product-by-process limitations have not been given patentable weight.

As stated above, the claims are directed to a product of white blood cells and a cyroprotective agent. First, applicant claims that the product is "less than all of plasma contained in said cord blood or placental blood, less than all of red blood cells contained in said cord blood or placental blood", thereby resulting in applicant is attempting to claim the product via the process of making the product. Second, applicant's claim that the product "has a white cell viability greater than 80% with respect to said cord blood or placental blood" or "a viability greater than 90% with respect to said cord blood or placental blood" is also a result of how the product was obtained and is seen to be applicant attempting to claim the product via the process of making the product. Third, applicant's claim that the product "contains less than 10% of red blood cells contained in said cord blood or placental blood" is seen to be applicant attempting to claim the product via the process of making the product. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

Also, applicant's claim that the product "has a white cell viability greater than 80% with respect to said cord blood or placental blood after freezing and thawing of the therapeutic product" or "a viability greater than 90% with respect to said cord blood or placental blood after freezing and thawing of the therapeutic product" is a recitation of

the intended use for the product and it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed product from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987). Further, applicant also claims that the white cell viability is tested using DNA fluorescence stain. This is a recitation of the intended use for the product and it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed product from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 29-32, 40, 44-47, 53, 57-60, 63, 67-70 & 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyse et al. ('681). Boyse et al. discloses the invention substantially as claimed, see rejection supra. Boyse et al., however, fails to disclose specifically the specific concentration of DMSO used (10% DMSO and 1% DMSO and diluted DMSO to 50% with dextran), the osmolarity of the product not more than 300 milliosmols and the volume of the product being contained in a volume of 3 mm to 20mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a concentration of DMSO to be either 1% or 10%, or diluted DMSO to 50% with dextran, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Therefore, since Boyse et al. discloses that a low concentration of DMSO is used such general conditions are met. With respect to the osmolarity of the product is not more than 300 milliosmols, it would have been obvious to one having ordinary skill in the art at the time the invention was made to achieve this osmolarity, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Further, it would obvious to one having ordinary skill in the art at the time the invention was made to have a product in a volume of 3 mm to 20 mm for storage, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the

optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

July 12th, 2004

PATRICIA BIANCO
PRIMARY EXAMINER

Patricia M Bianco
Primary Examiner
Art Unit 3762